

NOV 17 2004

3.0 510(k) Summary

Page 1 of 1

Sponsor: Synthes (USA)
1690 Russell Road
Paoli, PA 19301
(610) 647-9700

Device Name: Synthes Low Profile Neuro System

Classification: 21 CFR 882.5250: Cover, Burr Hole

Predicate Devices: Synthes Low Profile Neuro System

Device Description: The Synthes 1.6 mm burr hole covers come in various sizes to accommodate various fracture and osteotomy sites, have a low plate/screw head profile and use existing (previously cleared) 1.6 mm or 1.9 mm emergency self-tapping & self-drilling screws.

Intended Use: The Synthes Low Profile Neuro System is intended for use in selective trauma of the midface and craniofacial skeleton; craniofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.

**Substantial
Equivalence:** Comparative information presented supports substantial equivalence.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV 17 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Lisa Boyle
Regulatory Specialist
Synthes (USA)
1690 Russell Road
Paoli, Pennsylvania 19301

Re: K042986
Trade/Device Name: Synthes (USA) Low Profile Neuro System
Regulation Number: 21 CFR 882.5250
Regulation Name: Burr hole cover
Regulatory Class: II
Product Code: GXR, HRS
Dated: October 28, 2004
Received: October 29, 2004

Dear Ms. Boyle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

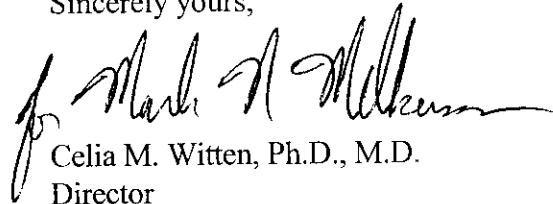
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over the typed name.

Celia M. Witten, Ph.D., M.D.
Director

Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.0

Indications for Use

510(k) Number (if known): _____

Device Name:

Synthes (USA) Low Profile Neuro System

Indications for Use:

The Synthes Cranial Plates are intended for use in selective trauma of the midface and craniofacial skeleton; craniofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.

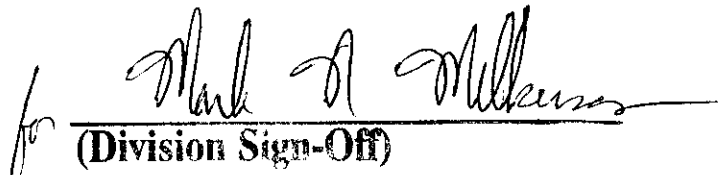
Prescription Use X
(Per 21 CFR 801.109)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
**Division of General, Restorative,
and Neurological Devices**

510(k) Number K042986

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